Appeal Brief

By: Philip E. Eggers, et al.

U.S. Serial No. 10/730,633

Filed December 8, 2003

"ELECTROSURGICAL APPARATUS AND SYSTEM WITH IMPROVED TISSUE CAPTURE COMPONENT"

Examiner Jeffrey Gerben Hoekstra

Group Art Unit 3736

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Real Party in Interest

The appealed application is assigned to Neothermia Corporation, now Intact Medical Corporation, a corporation of the State of Delaware, having an office at One Apple Hill, Suite 316, Natick, Massachusetts 01760.

Related Appeals and Interferences

There are no related appeals or interferences known to the Appellants, their legal representatives, or assignee, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal. However, an appeal with respect to the same application for patent and for the same claims has been submitted. This Notice of Appeal and Appeal Brief are provided in accordance with §1204.01 of the MPEP (reinstatement of appeal). A new Notice of Appeal accompanies this brief.

Status of Claims

The appealed application was filed December 8, 2003 with claims 1-29.

In an Office action mailed April 24, 2006, the Examiner identified 3 species and required Applicants to elect a single species for prosecution. The Examiner found no claim to be generic.

In a Response to Species Election dated May 19, 2006, Applicants elected with traverse Species I drawn to claims 1-12.

In an Office action mailed June 26, 2006, the Examiner made the species election final and withdrew claims 13-29 from consideration. The Examiner objected to claims 6, 7, and 9. Claim 1 was rejected on the ground of nonstatutory obviousness-type double patenting over claims 18, 26, 30 and 35 of U.S. Patent No. 6,287,304 B1. Claims 1, 3-4, and 12 were rejected on the ground of nonstatutory obviousness-type double patenting over claims 1, 5, 8, 15-17, 20, 22 and 23 of U.S. Patent No. 6,471,659 B1. Claim 1 was rejected on the ground of nonstatutory obviousness-type double patenting over claims 1 and 30 of U.S. Patent No. 6,923,809. Claim 1 was provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1 and 18 of co-pending application, U.S. Serial No. 10/630,336. Claims 1-5, 8, 11 and 12 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Published Application 2002/0072688 A1 by Burbank, et al. (hereinafter, referred to as "Burbank, et al."). Claims 6, 7, 9 and 10 were rejected under 35 U.S.C. § 103(a) over Burbank, et al.

In an Amendment and Response dated August 10, 2006, Applicant amended claim 11 and argued against the claim objections and rejections.

In an Office action mailed October 25, 2006, the Examiner maintained the nonstatutory obviousness-type double patenting rejection against claims 1, 3-4 and 12 over claims 1, 5, 8, 15-17, 20, 22 and 23 of U.S. Patent No. 6,471,659 B1. Additionally with respect to claim 1, the Examiner also maintained the nonstatutory obviousness-type double patenting rejection over claim 1 of U.S. Patent No. 6,923,809 and the provisional nonstatutory obviousness-type double patenting rejection over claim 1 of co-pending application Serial No. 10/630,336. The Examiner also maintained the rejection of claims 1-5, 7, 8, 11 and 12 under 35 U.S.C. § 102(b) as anticipated by Burbank, et al. Claims 6, 7, 9 and 10 also were rejected under 35 U.S.C. 103(a) as being obvious in view of Burbank, et al. All other grounds of rejection were withdrawn. These rejections were made final.

Claims 1-12 have been rejected. Claims 13-29 are withdrawn as being directed to the non-elected species. Applicants filed a Notice of Appeal April 25, 2007, which was received at the Patent Office April 27, 2007. An initial appeal brief was mailed on October 26, 2007. A non-

final Office Action was mailed January 16, 2008 reciting that claims 1, 3, 4 and 12 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 8, 15 -17, 20, 22 and 23 of U. S. Patent No. 6,471,659 B1. Claim 1 was rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U. S. Patent No. 6,923,809 B2. Claim 1 was rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U. S. Patent No. 6,955,653. Claims 1-5, 8, 11, and 12 are rejected under 35 U.S.C 102(e) as being anticipated by a new reference, McGuckin, Jr., et al., U.S. Patent No. 6,626,903 B2 (hereinafter McGuckin). Claims 6, 7, 9 and 10 were rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin. The appealed claims are claims 1-12.

In an Office communication mailed May 21, 2008 indicating that the most current Appeal Brief was defective inasmuch as it recited at page 5 of 19 that claims 13-22 were withdrawn for consideration whereas claims 13-29 were withdrawn. With respect to item (5) it was noted that the Arguments section referred back to the arguments presented in the Appeal Brief filed 10/29/07 and indicated it is unclear if in fact the Doubling Patenting rejection is being appealed. Part I of the Arguments section of this brief now states: “Upon an indication of allowable subject matter, applicants will submit a terminal disclaimer to obviate the Doubling Patenting rejections in view of U.S. Patent Nos. 6,471,659 B1; 6,923,809; and 6,955,653”. The Double Patenting rejection is not on appeal.

Status of Amendments

No amendments have been filed subsequent to the Office Action mailed January 16, 2008.

Summary of Claimed Subject Matter

Claim 1 is the only independent claim that is the subject of this appeal. Claim 1 generally is directed to electrosurgical apparatus for cutting about and retrieving a tissue volume with an improved capture component. This capture component generally is fashioned with a plurality of thin elongate leafs which extend from a base portion to tip regions having cable guide outlets. A pursing cable assembly configured with a plurality of electrosurgically energizable stainless steel multi-strand braided cables is supported by the multi-leaf structure in a manner wherein the cables are maneuvered through the guide outlets to establish a cutting leading edge which envelopes a target tissue volume as the moving leafs progressively assume the configuration of a tissue capturing cage.

Claim 1 first recites a support member having an internal channel. Such a support member is shown, for example, in Fig. 1 at 32 and described at page 9, lines 17-19. Within the interior channel of the support member is the improved tissue capture component, which is best illustrated in Figs. 9-12 at 340 and described at page 20, line 24 to page 21, line 34. Looking to that portion of the specification and Fig. 10, it may be seen that tissue capture component 340 includes a leaf assembly with a plurality of elongate thin leafs, 300-304, each extending from a base portion 342 to a leaf tip region 344. The embodiment illustrated comprises a leaf assembly with 5 leafs. Each leaf includes a drive component, 350-354, extending along a leaf axis, 356. Each leaf is encased within an electrically insulative flexible leaf cable guide component, 400-404. Fig. 9, shows the leafs of Fig. 10 encased with cable guide components, one of which is illustrated in Fig. 12. As shown in Fig. 12, each of the cable guide components includes a guide channel such as 414 extending to a guide outlet such as 416 in Fig. 16. Cable guide component 400 of Fig. 12 also includes coupling mount 406. Guide channel 414 extends from tip region 344 along the drive component to a guide commencement location 364 (Fig. 10). As described at page 13, lines 5-6 of the specification, the leaf assembly is deployed outwardly from the support member 32. Tissue capture component 340 also includes a pursing cable assembly extending through the cable guide component guide channel 414 and guide outlet 416.

As described at page 22, lines 6-22, the cable assembly employed with capture component 340 is comprised of five cables. These cables extend through support member 32 to enter the guide channel (e.g., 414 in Fig. 12) of a given leaf whereupon it exits from the guide outlet (e.g., 416 in Fig. 16) and is introduced into the guide outlet of a next adjacent leaf, whereupon it extends through the associated channel to a connection located rearwardly of the guide commencement location. Connection is made by fashioning an enlargement such as a

knot or weld ball at the end of the cable. That cable terminus then is inserted through a connector slot (428 in Fig. 15). Looking to Fig. 15, a cable 420 is seen extending into guide channel 408. That cable will exit from guide outlet 416 and reenter the guide outlet of a next adjacent leaf. In this regard, Fig. 15 shows the cable 424 from a next adjacent leaf as having entered guide outlet 416 and extends to an enlargement 426 at its terminus which has been inserted into a keyway shaped slot 428. Each leaf of the capture component 340 is configured in the same manner. Fig. 19 reveals cables 420 and 424 within the channel 414 of guide channel 408.

The pursing cable assembly is electrosurgically energizable and deployable with each leaf tip region 344 to define an electrosurgical cutting arc of initially expanding extent and subsequently pursively contracting extent. Fig. 20 illustrates the tissue capture component 340 in an initial position prior to deployment. In Fig. 21 the orientation of the capture component 340 is illustrated as it extends about one half of the available total axial distance from the instrument forward region 34. Fig. 5 illustrates a fully deployed orientation wherein the leaf tip portions converge at a capture position defining a capture basket configuration or tissue recovery cage substantially encapsulating the entire target tissue volume.

Grounds of Rejection to be Reviewed on Appeal

Whether claims 1-5, 8, 11 and 12 are unpatentable under 35 U.S.C. § 102(e) in view of McGuckin.

Whether claims 6, 7, 9 and 10 are unpatentable under 35 U.S.C. §103(a) in view of McGuckin.

Argument

I. Double patenting

Applicants' statement at page 10 of 20 of the original brief is incorporated herein by reference. "Upon an indication of allowable subject matter, applicants will submit a terminal disclaimer to obviate the Doubling Patenting rejections in view of U.S. Patent Nos. 6,471,659 B1; 6,923,809; and 6,955,653". The Double Patenting rejection is not on appeal.

II. Claims 1-5, 8, 11 and 12 are not anticipated by McGucken

At the outset reference is made to page 7, lines 3 through 8 of the application which describe that with the present invention, a forwardly disposed stainless steel guide support region of each leaf is formed with a diminished widthwise extent and is enclosed within an extruded polymeric cable guide. This not only provides an improved leaf cable guide function but permits enhanced flexure at the tip region of each leaf. That enhanced flexure promotes a steeper angle of attack during the pursing activity to, in turn, improve the cutting profile of the advancing and pursing cutting cable leading edge. By applying the instant rejection, the Examiner has simply paraphrased the applicants claims and shoehorned claim terminology into the McGuckin reference. McGuckin is not describing thin resilient leafs, it is describing outer (female) rails 50 and inner tissue penetrating rails (column 6, lines 37-42). As set forth at column 8, line 32, these inner and outer rails are described as having blunt tips but alternately to reduce the tissue penetrating forces they may have sharper pointed tips. That means they have to withstand penetrating into flesh forces without the help of a cable implemented electrosurgical cutting element as present in the present invention. At column 8, lines 40-41, the patent describes that "... the outer and inner rails are preferably made of shaped memory metal material such as Nitinol, ...". Thus, when they are exposed to body heat presumably during penetration, they take the curved shape shown in the patent. They don't flex, they are rails. At paragraph 8 of the Office Action, the Examiner recites a plurality of elongate thin leafs (160). Further paraphrasing claim 1, the Examiner states that a said leaf having a resilient metal drive component (170). The patent describes component 170 as a carrier and in fact, it carries an electrosurgical wire 186 after the penetration into flesh of rails 160. Rails 160 must be rigid in order for the disclosed system to operate. The carriers 170 also drag a "suture" and collection bag 182. That's not a thin leaf which is pursed.

Claim 2, dependent upon claim 1 describes that the leaf drive component is formed of a resilient metal having a first width at the base portion extending at least to the guide commencement location and that the cable guide component is formed of a polymeric material.

There is no discussion of a polymeric material in McGuckin. The metal is not resilient, it must be stiff.

Claim 3, dependent upon claim 2 sets forth that the leaf cable guide component coupling portion is configured as a sheath surmounting the drive component. That's what is seen in Fig. 12 at 410. McGuckin can't possibly be construed to incorporate those components.

Claim 4, dependent upon claim 3 describes that the leaf drive component first width is defined between oppositely disposed edges extending from the base portion to the guide commencement location and is configured having a second full width less than the first width extending from the guide commencement location to the tip region. That points out one of the advantages of the invention, i.e., more flexibility in connection with the leaf structure of the capture component.

Claim 5 dependent upon claim 3 recites that the leaf drive component is configured having at least one serrated edge. There are no serrated edges as much as suggested in McGuckin.

Claim 7, dependent upon claim 6 recites that each leaf cable guide coupling portion oppositely disposed rearward end surface has a widthwise extent of about 0.010 inch. There is no such dimension in McGuckin.

Claim 8, dependent upon claim 2 describes that the cable guide component is a guide channel configured to surround one or more cables of the pursing cable assembly. Look for example, to Fig. 19 and item 414. There is no such structure whatsoever suggested in McGuckin. There is no pursing in the reference.

Claim 11, dependent upon claim 1, recites that the leaf cable guide component is formed of polymeric material and that each guide channel is reinforced in the vicinity of the guide outlet to an extent effective to avoid damage occasioned during deployment of the cable assembly. There is no such structure as much as suggested in McGuckin.

Claim 12, dependent upon claim 11 recites that the leaf resilient drive component is formed of metal as configured to define a protective aperture extending across the guide outlet at the tip region. There is no protective aperture so much as suggested in McGuckin.

III. Claims 6, 7, 9 and 10 are patentable and unobvious over McGuckin

As described in detail above, McGuckin fails to disclose most of the features of claim 1. No additional references have been cited that disclose, either alone or in combination, the recited features of claim 1 that McGuckin lacks. For that reason alone, claim 6, 7, 9 and 10 should be considered patentable over McGuckin. McGuckin also fails to disclose the additional

features recited in claims 2-4 from which claims 6, 7 and 9 depend and claim 2 from which claim 10 depends.

Claim 6, dependent upon claim 4 recites that the leaf drive component first width is about 0.080 inch and that the leaf drive component second full width is about 0.060 inch. It is submitted that McGuckin would not work with those dimensions or with leafs.

Claim 7, dependent upon claim 6 recites that each leaf cable guide coupling portion oppositely disposed rearward end surface has a widthwise extent of about 0.010 inch. Notwithstanding the question of operability of McGuckin with such dimensions, there is no leaf cable guide as much as suggested in McGuckin.

Claim 9, dependent upon claim 8 describes that the guide channel exhibits an internal diametric extent of about 0.015 inch. There is no guide channel in McGuckin.

Claim 10, dependent upon claim 2 describes that the leaf cable guide component polymeric material is polytetrafluoroethylene. As noted above, that reduces friction as the thin resilient leafs are driven from the forward tip of the instrument. There is no suggestion nor mention whatsoever of such materials or such a function in McGuckin.

Conclusion

Accordingly, Appellants respectfully urge the Board to overrule the rejection of the appealed claims and to permit the appealed application to pass to issue.

Respectfully submitted,

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Claims Appendix

Claim 1 (original) Apparatus for electrosurgically cutting about a tissue volume, comprising:

a support member having an internal channel and extending to a forward region;

a tissue capture component positioned within said interior channel, having a leaf assembly comprising a plurality of elongate thin leafs extending forwardly from a base portion to a leaf tip region, a said leaf having a resilient drive component extending along a leaf axis from said base portion to a tip region, and an electrically insulative flexible leaf cable guide component having one or more guide channels deposed parallel with said leaf axis and extending to a guide outlet, and an integrally formed coupling portion mounted with said drive component, a said guide channel extending from said tip region along said drive component to a guide commencement location, said leaf assembly being moveable to deploy outwardly from said support member forward region, said capture component having a pursing cable assembly extending through a said cable guide component guide channel and said guide outlet, electrosurgically energizable and deployable with each said leaf tip region to define an electrosurgical cutting arc of initially expanding extent and subsequent pursively contracting extent;

a drive assembly engageable with said leaf assembly base portion and said pursing cable assembly and actuable to move said leaf assembly to deploy outwardly from said support member while effecting said deployment of said pursing cable assembly; and

a control assembly drivably engageable with said drive assembly to effect said actuation thereof and having a terminal electrically coupled with said cable assembly to effect the electrosurgical energization thereof.

Claim 2 (original) The apparatus of claim 1 in which:

said leaf drive component is formed of a resilient metal having a first width at said base portion extending at least to said guide commencement location; and

said leaf cable guide component is formed of polymeric material.

Claim 3 (original) The apparatus of claim 2 in which:

said leaf cable guide component coupling portion is configured as a sheath surmounting said drive component.

Claim 4 (original) The apparatus of claim 3 in which:

said leaf drive component first width is defined between oppositely disposed edges extending from said base portion to said guide commencement location, and is configured having a second full width less than said first width extending from said guide commencement location to said tip region and defining with said first width oppositely disposed shoulders at said guide commencement location; and

said leaf cable guide coupling portion is configured having oppositely disposed rearward end surfaces at said guide commencement location extending in abuttable support before said oppositely disposed shoulders.

Claim 5 (original) The apparatus of claim 3 in which:

said leaf drive component is configured having at least one serrated edge with rearwardly directed points engageable with said sheath configured to engage said leaf cable guide component coupling portion when said leafs are moved rearwardly from a deployed orientation toward said support member.

Claim 6 (original) The apparatus of claim 4 in which:

said leaf drive component first width is about 0.080 inch; and

said leaf drive component second full width is about 0.060 inch.

Claim 7 (original) The apparatus of claim 6 in which:

each said leaf cable guide coupling portion oppositely disposed rearward end surface has a widthwise extent of about 0.010 inch.

Claim 8 (original) The apparatus of claim 2 in which:

said leaf cable guide component has one said guide channel configured to surround one or more cables of said pursing cable assembly between said guide outlet and said guide commencement location.

Claim 9 (original) The apparatus of claim 8 in which:

said guide channel exhibits an internal diametric extent of about 0.015 inch.

Claim 10 (original) The apparatus of claim 2 in which:

said leaf cable guide component polymeric material is polytetrafluoroethylene.

Claim 11 (original) The apparatus of claim 1 in which:

said leaf cable guide component is formed of polymeric material; and

each said guide channel is reinforced in the vicinity of said guide outlet to an extent effective to avoid damage occasioned during the deployment of said cable assembly.

Claim 12 (original) The apparatus of claim 11 in which:

said leaf resilient drive component is formed of metal and is configured to define a protective aperture extending across said guide outlet at said tip region.

13. (withdrawn) A system for retrieving a tissue volume, comprising:

a support assembly with an interior channel extending along an instrument axis to a forward region;

a capture component positioned within said interior channel, having a leaf assembly comprising a plurality of thin leafs arranged in mutual adjacency for cage definition, extending from a base portion to a leaf tip region, a said leaf having a resilient drive component extending along a leaf axis from said base portion to a tip region, and an electrically insulative flexible leaf cable guide component having one or more guide channels disposed parallel with said leaf axis and extending to a guide outlet at said leaf tip region and an integrally formed coupling portion mounted with said drive portion, a said guide channel extending from said tip region guide outlet along said drive component to a guide commencement location, said capture component having a pursing cable assembly comprising electrosurgically energizable cables, each said cable extending from a cable terminator through a said guide channel and its associated guide outlet at one said leaf and thence into a said guide outlet and associated guide channel at a next adjacent said leaf and extending therethrough to a connection with the drive component thereof, said capture component base portion being drivable to extend said leafs from an initial position generally within said interior channel outwardly and forwardly toward an expanded orientation, said cables being loadable in tension to effect a pursing of said leaf tip regions from said expanded orientation toward said instrument axis to exhibit a capture orientation;

a support assembly configured to support said cable terminator for slideable forward movement under drive from said cables;

a drive assembly having a drive member drivably engaged with said capture component base portion and actuable to apply said drive thereto;

a cable stop located to effect blockage of said slideable forward movement of said cable terminator at a location effecting the loading of said cables in tension; and

a control assembly controllable to effect said electrosurgical energization of said cables and actuation of said drive assembly.

14. (withdrawn) The system of claim 13 in which:

said cable connection with said drive member is located rearwardly of said guide commencement location.

15. (withdrawn) The system of claim 14 in which:

said cable connection comprises a key slot formed through said drive component; and

an enlargement at the terminus of an associated said cable extending through and engaged by said key slot.

16. (withdrawn) The system of claim 13 in which:

said leaf cable guide component is formed of polymeric material; and

each said guide channel is reinforced in the vicinity of said guide outlet to an extent effective to avoid damage occasioned during the deployment of said cable assembly.

17. (withdrawn) The apparatus of claim 16 in which:

said leaf resilient drive component is formed of metal and is configured to define a protective aperture extending across said guide outlet at said tip region.

18. (withdrawn) The apparatus of claim 13 in which:

said leaf drive component is formed of a resilient metal having a first width at said base portion extending at least to said guide commencement location; and

said leaf cable guide component is formed of polymeric material.

19. (withdrawn) The apparatus of claim 18 in which:

said leaf cable guide component coupling portion is configured as a sheath surmounting said drive component.

20. (withdrawn) The apparatus of claim 19 in which:

said leaf drive component first width is defined between oppositely disposed edges extending from said base portion to said guide commencement location, and is configured having a second full width less than said first width extending from said guide commencement location to said tip region and defining with said first width oppositely disposed shoulders at said guide commencement location; and

said leaf cable guide coupling portion is configured having oppositely disposed rearward end surfaces at said guide commencement location extending in abuttable support before said oppositely disposed shoulders.

21. (withdrawn) The apparatus of claim 18 in which:

said leaf cable guide component polymeric material is polytetrafluoroethylene.

22. (withdrawn) A system for retrieving a tissue volume, comprising:

a support assembly with an interior channel extending along an instrument axis to a forward region;

a capture component positioned within said interior channel, having a leaf assembly comprising a plurality of thin leafs extending forwardly from a base portion to a leaf tip region, a said leaf having a resilient drive component extending along a leaf axis from said base portion to a tip region, and an electrically insulative flexible leaf cable guide component having one or more guide channels disposed parallel with said leaf axis and extending to a guide outlet, and an integrally formed coupling portion mounted with said drive component, a said guide channel extending from said tip region along said drive component to a guide commencement location, said leaf assembly being drivable to deploy outwardly from said support member forward region, said capture component having a pursing cable assembly comprising electrosurgically energizable cables, each said cable extending from a cable terminator through a said cable guide component guide channel and guide outlet and being deployable with each leaf tip region to define an electrosurgical cutting arc of initially expanding movement and subsequent contracting movement as said leaf tip regions mutually converge toward a capture complete basket defining orientation;

a drive assembly having a drive component drivably engaged with said capture component base portion and extending to connection with a drive member, and a motor drive assembly energizable to impart forward drive movement to said drive member to effect application of drive to said capture component and exhibiting a stall condition when said forward drive movement of said drive member is terminated;

a support assembly configured to support said cable terminator and said drive member for slideable forward movement;

a cable stop located to effect blockage of said slideable forward movement of said cable terminator to effect said arc contracting movement;

a drive member stop located to effect blockage of said slideable forward movement of said drive member in correspondence with said capture complete basket defining orientation to effect said stall condition; and

a control assembly controllable to effect said energization of said motor drive assembly and said cables, and to de-energize said cables and said motor drive assembly in response to said stall condition.

23. (withdrawn) The system of claim 22 further comprising:

a safety stop located forwardly of said drive member stop to effect blockage of said slideable forward movement of said drive member in the event of a failure on the part of said drive member stop to do so.

24. (withdrawn) The system of claim 23 in which:

said safety stop is located in substantially close proximity to said drive member stop.

25. (withdrawn) The apparatus of claim 22 in which:

said leaf drive component is formed of a resilient metal having a first width at said base portion extending at least to said guide commencement location; and

said leaf cable guide component is formed of polymeric material.

26. (withdrawn) The apparatus of claim 25 in which:

said leaf cable guide component coupling portion is configured as a sheath surmounting said drive component.

27. (withdrawn) The apparatus of claim 26 in which:

said leaf drive component first width is defined between oppositely disposed edges extending from said base portion to said guide commencement location, and is configured having a second full width less than said first width extending from said guide commencement location to said tip region and defining with said first width oppositely disposed shoulders at said guide commencement location; and

said leaf cable guide coupling portion is configured having oppositely disposed rearward end surfaces at said guide commencement location extending in abuttable support before said oppositely disposed shoulders.

28. (withdrawn) The apparatus of claim 27 in which:

said leaf drive component is configured having at least one serrated edge with rearwardly directed points engageable with said sheath configured leaf cable guide component coupling portion when said leafs are moved rearwardly from a deployed orientation toward said support member.

29. (withdrawn) The apparatus of claim 27 in which:

said leaf drive component is configured having an effective width less than said second full width extending from said guide commencement location to said tip region.

Evidence Appendix

None.

Related Proceedings Appendix

None.